

EDITORIAL COMMENT

Percutaneous Coronary Intervention Without Onsite Cardiac Surgery

Ready for Take-Off?*

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The first nonstop transatlantic crossing occurred in 1919, in a World War I-era twin-engine biplane flown by British aviators from St. John's, Newfoundland, to Galway, Ireland, in over 16 h (1), launching an era of long-distance air travel. In 1953, given the unreliability of early airplane engines, aviation authorities restricted 2-engine airplanes to routes within short range of “diversion” airports where a disabled plane could fly to safety (2). As engine reliability improved and engine failure became increasingly rare, these precautions seemed outdated. In 1985, the U.S. Federal Aviation Administration developed a program that included rigorous maintenance and operational procedures to certify twin-engine jets to fly extended-range journeys (3). This opened more direct air routes to smaller, more efficient planes and expanded access to nonstop routes worldwide (3).

Similarly, percutaneous coronary intervention (PCI), first introduced nearly 4 decades ago by pioneer Andreas Grüntzig (4), launched dramatic growth in coronary revascularization. Initially limited to balloon angioplasty of proximal stenoses in large vessels, with an operating room and cardiothoracic surgeon on standby in case of procedural complication requiring emergency coronary artery bypass surgery (CABG), PCI has evolved to include multiple devices in the treatment of complex coronary anatomy. The advent of stents and improvements in device technology, procedural technique, and

adjunctive pharmacotherapy, as well as increased operator experience, have reduced the incidence of emergency CABG after PCI from a range of 6% to 10% to a range of 0.1% to 0.3% (5-7). As a result, coupled with the mandate for improved access to prompt primary PCI for acute ST-segment elevation myocardial infarction (STEMI), the cardiovascular community has seen the growth of facilities that perform PCI without onsite cardiac surgery. Of all reporting facilities performing PCI in the United States in 2004, 8.7% did not have onsite cardiac surgery compared with 32.6% in 2011, with a corresponding rise in the proportion of PCI procedures performed in these facilities, from 3.9% of total PCI procedures reported in 2005 to 12.4% in 2011 (5,8). Both in the United States and in the United Kingdom, these numbers continue to rise. Randomized controlled trials examining the safety of this practice for nonemergency PCI have reported noninferiority of procedures performed at sites without compared with those with onsite cardiac surgical services with respect to short- and intermediate-term outcomes (9,10).

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In this issue of the *Journal*, Garg et al. (11) report the results of a retrospective analysis of outcomes of 384,013 PCI procedures tracked by the national British Cardiovascular Intervention Society database between 2006 and 2012, of which 119,096 (31%) were performed in hospitals with offsite surgical support. Patients undergoing PCI at centers with offsite surgical support were older, with a higher prevalence of female sex, prior revascularization, peripheral vascular disease, and left ventricular dysfunction, whereas patients treated at centers with onsite surgical support were more likely to undergo PCI for STEMI, multivessel disease, and bypass graft lesions, as well as PCI with circulatory support, and to undergo

*Editorials published in the *Journal of the American College of Cardiology* reflect the views of the authors and do not necessarily represent the views of JACC or the American College of Cardiology.

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emergency CABG. The primary endpoint of the study, all-cause mortality rate at 30 days, was lower in patients treated in centers with offsite compared with onsite surgical support (2.0% vs. 2.2%; $p < 0.001$), although unadjusted Kaplan-Meier survival curves revealed increased survival for patients with stable angina and decreased survival for patients with non-STEMI and STEMI at centers with offsite surgical support. Multivariable adjustment performed to account for confounders revealed no difference in hazard ratios for mortality between groups at 30 days and 1 and 5 years, irrespective of procedural indication, and these comparable survival rates were confirmed in a sensitivity analysis of a propensity-matched cohort of 74,001 patients. The authors concluded that PCI performed at centers without onsite surgical support is not associated with a mortality hazard.

Although not randomized, this study contributes a large dataset that consists of a mandated national registry that compares patients arriving and being treated at both centers with and without onsite cardiac surgery. In reality, a trial designed to best answer the question, one that randomizes patients on arrival at centers both with and without onsite cardiac surgery to PCI at centers both with and without onsite cardiac surgery, is very unlikely to be performed. Of note, the randomized trials compared a strategy of the transfer of patients for PCI to a hospital with onsite surgical support to that of the performance of PCI at the initial hospital without onsite support (9,10).

Several caveats inherent to the nature of the study and limitations of the database are noteworthy. First, results are limited to mortality (albeit, arguably most important). Other outcomes, including complete or repeat revascularization and incidence of transfer from offsite to onsite cardiac surgery facilities, as well as the incidence of complications such as recurrent myocardial infarction, stroke, or bleeding, are unavailable. These nonfatal endpoints are of interest when one considers the effectiveness and safety of a new practice pattern. Second, the randomized trials specified rigorous pathways and standards for PCI program development, including mandated staff training, operator certification, quality management, and PCI volume requirements for institutions planning PCI without onsite cardiac surgery. The current study, retrospective in character, does not engage in the question of program development for expansion of PCI.

Notwithstanding the above concerns, these data add to a growing body of evidence that suggests that PCI procedures performed at facilities without versus those with onsite cardiac surgery are comparable in safety. Yet several issues will still need ongoing

thoughtful consideration. Atomization of PCI volume and experience, with a growing number of procedures being performed at an increasing number of low-volume centers, remains a concern (5). Given the association of PCI volume and outcomes, monitoring volumes and performance in the midst of this growth is in the public interest (12-14). Interestingly, data presented by Garg et al. (11) indicate that the growth of the centers without onsite cardiac surgery did not come at the expense of centers with onsite surgical support; the onsite centers maintained stable volumes, while the offsite centers continued to grow. These findings may reflect system-specific features (e.g., new centers serving underserved areas and a national health system with long wait times for procedures) not reproducible in the United States, where cannibalization of volume within a region has the potential to threaten both quality and fellow training (as PCI procedures move away from full-service centers with approved training programs). Moreover, in an increasingly cost-conscious environment, expanded PCI programs will likely need to demonstrate additional access to care and procedural appropriateness and not mere duplication of services.

Additionally, the benefits of onsite cardiac surgery go beyond the proximity of the operating theater. Rather, they also imply the presence of an interdisciplinary “heart team,” as recommended by revascularization guidelines (15-17). At its best, such a team works together to determine the ideal approach for patients with complex coronary disease and may offer patients the fullest range of options. Although current communication technology may allow for an improvised virtual heart team, it is unclear whether PCI facilities without onsite cardiac surgery can incorporate surgical counsel from partnering institutions and provide a comparable experience for optimal patient care.

When faced with changes in the practice of medicine, like aviation, we generally favor conservative approaches. Safety is paramount, and the medical community is reluctant to withdraw a safety net until a compelling new paradigm of need and safety can be put in its place. Gathering evidence has leaned opinion in the cardiovascular community toward expansion of PCI to facilities without onsite cardiac surgery, but we must take steps to ensure that this occurs in the context of appropriate standards and program development to best serve and protect our patients.

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KEY WORDS cardiac surgery onsite, coronary angioplasty, coronary artery disease